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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 08/894,356 | 08/18/97 | ASHIKARI T | 001560-308 |

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|---|---|
| ZAGHMOUT, O | |
| **ART UNIT** | **PAPER NUMBER** |
| 1649 | 20 |

**DATE MAILED:** 02/10/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 08/894,356 | Ashikari et al |
| **Examiner** | **Group Art Unit** |
| Ousama Zaghmout | 1649 |

☒ Responsive to communication(s) filed on *Aug 18, 1997*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-45* is/are pending in the application.

Of the above, claim(s) *13-19 and 21* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-12, 20, and 22-45* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*— SEE OFFICE ACTION ON THE FOLLOWING PAGES —*

## Detailed Office Action

I. The amendment and the declaration filed 10-12-1999 have been received and entered [Paper No.19].

II. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

III. Status of the claims:

Claims 1, 4, 7, 24-25 have been amended.

Claims 28-45 have been added.

Claims 1-12, 20, 22-45 are under consideration on the merits. Claims 13-19, 21 were withdrawn from consideration in the previous Office action as they are drawn to non-elected inventions.

Claims 1-45 are pending.

IV. This application contains claims 13-19, 21 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

V. The claims are objected to for minor typographical errors:

Claim 24, line 2: The word " antocyanin" should be "anthocyanin".

Claim 28, line 5: "SSD" should be "SDS".

Applicants are respectfully requested to correct these and to review the entire specification for similar errors.

VI. Please find enclosed a copy of the Raw Sequence Listing Error Report.

VII. To clarify the following claims, Applicants are respectfully requested to amend:

Claim 20, line 4, by replacing "acylating" with "acylate";

Claim 22, line 4, by replacing "acylating" with "acylate";

Claim 23, line 4, by replacing "acylating" with "acylate";

Claim 33, line 3, by replacing "acylating" with "acylate";

Claim 34, line 3, by replacing "acylating" with "acylate".

VIII. In claim 27, line 2, Applicants are respectfully requested to clarify if the intended meaning of the phrase "the same property" is "an enzymatic activity".

## Claim Rejections - 35 U.S.C. § 112

### Ist Paragraph

Claims 1-12, 20, 22-27 remain rejected and newly added claims 28-45 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the

time the application was filed for the reasons of record stated in the previous office action mailed 2-12-1999.

Applicants argue that Applicants have disclosed many cDNA's which encode an enzyme having an aromatic acyl group transfer activity, and the specification describes the cDNA's which have been cloned as shown in Examples 6, 8, 20, 11, 12 (last paragraph in page 6 bridging the first paragraph in page 7). Applicants further argue that one of skill in the art could use the teachings from these Examples to obtain a protein having an aromatic acyl group transfer activity of any origin. (second paragraph, page 2). These arguments have been carefully considered, but not found persuasive.

1. The teaching cited in the above cited Examples can be used only to isolate nucleotide sequences which encode one single enzyme from a number of plant species, namely acyltransferase from the anthocyanin pigment. This is mainly because the chemical properties and the physical characteristics of these proteins and nucleotide sequences are very similar. However, the pigment anthocyanin has more than one acyltransferase enzyme, depending ~~depends~~ on the chemical structure of the enzyme (e.g., anthocyanin 5-aromatic acyltransferase). The question is whether nucleotide sequences of other acyltransferases are the same or similar to those exemplified in the specification. Neither the specification nor the prior art provides any teaching regarding the other nucleotide sequences. Moreover, the specification does not teach if the nucleotide sequences disclosed in the specification are the same or identical to the nucleotide sequences which encode proteins of other pigments (e.g., chlorophyll, carotenoid, accessory pigments, and phycobilin) which have acyltransferases.

The specification does not teach if the nucleotide sequences which encode the aromatic acyl group transfer activity are conserved among all proteins which exhibit ~~said~~ the activity.

The teaching disclosed in the Examples cited above can be used to isolate nucleotide sequences which encode one protein from a number of plant species. Since not all proteins which exhibit acyltransferase activity are identical, the nucleic acid sequence and amino acid sequences are not expected to be identical either. In order to be able to claim the genus, Applicants are required to isolate nucleotide sequences of different proteins which exhibit acyltransferase activity, not of the same protein, from a number of plant species. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art to make and use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate.

2. Applicants stated that in Example 11, sequences of the amino acids are highly conserved between these proteins. This is not found persuasive as all of these sequences relate to a single protein as described above. These amino acid sequences are highly conserved for the same protein isolated from a number of plant species. However, the

claimed subject matter encompasses more than one single protein with acyltransferase activity of the anthocyanin pigment. Those of skill in the art can use primers ~~form~~ from SEQ ID: 1-6 to isolate only additional sequences that are very similar to sequences of SEQ ID: 1-6, not different sequences. Applicants have not shown that this is not the case in the instant application. Subsequently, the specification of the instant application satisfies only the written description for one gene which encodes a specific acyltransferase of the anthocyanin pigment.

II. Claims 1-12, 20, 22-27 remain rejected and newly added claims 28-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabled only for isolation of the nucleotide sequence identified in SEQ ID NOs: 1-6 which encode a protein having aromatic acyl group transfer activity, for the construction and introduction of the acyltransferase gene into petunia, and for the reasons of record detailed in the previous Office action for claims 1-12, 20, 22-27, pages 7-10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants allege that the Examiner has not met the burden of establishing that the claims are not enabled by the specification. Applicants have not pointed out where in the Office action the Examiner has failed to show that the invention as claimed is not enabled. The Examiner pointed out that the specification does disclose only the isolation of the nucleotide sequences identified in SEQ ID NOs: 1-6 which contain nucleotide sequences that encode a protein having aromatic acyl group transfer activity, and for the construction and introduction of the acyltransferase gene into petunia. Applicants have neither shown if these genes are the

same in other acyltransferases from other pigments nor if these genes are the same for all acyltransferases of the anthocyanin pigment. None of these genes were expressed at the plant level. The specification clearly states in lines 31-32, page 39 that " the result indicates that the gene of acyltransferase of gentians could be introduced into the rose". The specification does not teach if acyltransferase genes were expressed at the plant level to a level whereby the desired phenotype was obtained. As explained in the previous Office action, that integration of a gene does not mean that an expression of a phenotype from said gene will be obtained. Subsequently, the rejection is maintained.

**2nd Paragraph**

I. The rejection of claim 1 and dependent claims 2-12, 20, 22-27 for the use of the word " derivative" which render these claims vague and indefinite has been withdrawn in view of the amendment of claim 1.

II. Claim 4 remains rejected for the use of the word " modified" which renders the claim vague and indefinite for the reasons mentioned in the previous Office action.

III. Claim 4 remains rejected for the use of the word " addition or removal of one or more amino acids" which renders this claim vague and indefinite for the same reasons mentioned in the previous Office action.

IV. Claim 4 remains rejected for the use of the word " substitution" which renders this claim vague and indefinite for the same reasons mentioned in the previous Office action.

The vague and indefinite words cited in claim 4 have not been clarified in Applicants' remarks in order to overcome the deficiency in the specification. In addition, Applicants have not clarified in the specification what amino acid can be changed or what amino acid residue can be included or excluded from these alterations. These words remain vague and indefinite.

V. Claim 6 remains rejected for the recitation of " with part " which renders this claim vague and indefinite for the same reasons mentioned in the previous Office action.

Applicants argue that the term "with part" is defined in the specification as in page 34, lines 25-34 and that this part is highly conserved. This is not found persuasive as Applicants are arguing limitations that are not in the claim. Furthermore, it not clear from the specification that this is the only meaning of this term. The term was not defined in the specification in a clear and concise manner where the metes and the bounds can be defined by a person with skill in the art.

VI. The rejection of claims 7 and 25 for the use of the word " having" which renders this claim indefinite has been withdrawn in view of the amendment of the claims.

VII. The rejection of claims 7-8 as being vague and indefinite has been withdrawn upon consideration of the record.

VIII. Claims 22 and 33 are rejected under 35 USC 112 2nd as being redundant. The same method is claimed by claims 22 and 33. Cancellation of one of the claims will obviate the rejection.

IX. Claim 25 is rejected under 35 USC 112 2nd as being vague for the recitation of " which has its colored controlled". A clarification is requested. Furthermore, Applicants are requested to clarify the language in lines 1-2 of the claim. The claim reads now that the color has been controlled by "its progeny".

## Claim Rejections - 35 USC § 102

The rejection of claims 1-8 under 35 U.S.C. 102(b) as being clearly anticipated by Ishizaki et al (FEBS Lett 1988 Oct 10;238(2):424-430) has been withdrawn in view of the amendment of claim 1.

## Claim Rejections - 35 USC § 103

The rejection of claims 1-12, 20, 22-27 under 35 U.S.C 103 (a) as being unpatentable over Ishizaki et al (FEBS Lett 1988 Oct 10;238(2):424-430) in view of Heidmann et al (Nature. 1987. Vol. 330:677-678), Matern et al (Arch. Bioch. Biophys. 1981. Vol.208:233) and Kamsteeg et al (Biochem. Physiol. Pflanzen. 1980. Vol. 175: 403) has been withdrawn in view of the amendment of claim 1.

## Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**Future Correspondence**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, L. Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

January 13, 2000

L. F. Smith

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